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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/655,232	09/05/2000	Stewart M. Kume	SMP0179US02	7770

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EXAMINER

MENDEZ, MANUEL A

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/655,232

Applicant(s)

KUME, STEWART M.

Examiner

Manuel Mendez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-9, 13-21 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-9, 13-21, and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

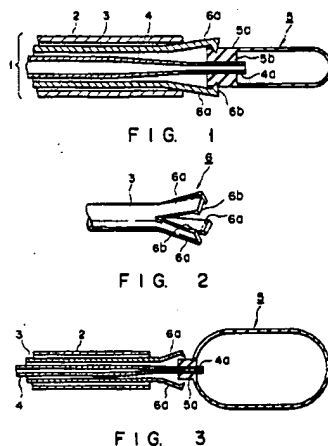
- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-9, 13-21, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishida, et al., in view of Tanabe et al., and Becker et al.



Ishida et al., shows an elongate catheter body, an expandable member attached to a distal end of the catheter body; and opaque markers positioned on the expandable member. In column 4, line 19, the specification states: "the material of the balloon (5) may be mixed with X-ray opaque substance such as platinum, gold or the like which constitutes a marker".

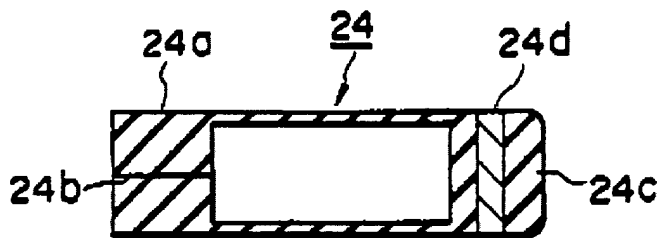


FIG. 11

Moreover, in column 6, line 55, referring to figure 11, the specification states: "the distal portion (24c) of the balloon (24) may be made solid, and a belt-type marker (24d) made of x-ray opaque substance as described above may be fixed to or embedded in the outer peripheral surface portion (24c)". Based on the teachings of Ishida et al., the use of markers in a balloon is conventional in the art. However, the applicant discloses a plurality of markers arranged in a pattern.

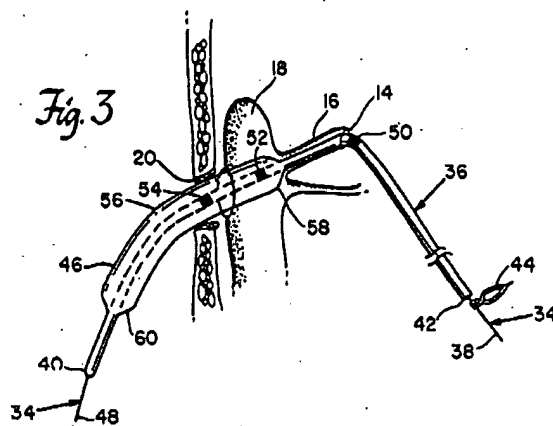
Importantly, even do Ishida et al., does not disclose a plurality of markers, it is well established in case law that the mere duplication of a well known element (opaque markers) in an apparatus does not constitute patentable subject matter. Moreover, in this particular case, the use of opaque markers in a catheter arranged in a particular pattern is well known in the art as evidenced by Tanabe et al.

Therefore, for a person of ordinary skill in the art, modifying the balloon disclosed by Ishida et al., with multiple markers arranged in a pattern would have been considered obvious because such configuration would have enhanced the capabilities of the

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catheter system and the accuracy of localizing the catheter after deployment to the body.

Finally, neither Ishida et al., nor Tanabe et al., teach the use of ink as a marker. However, the use of ink as a marker is conventional in the art as evidenced by the teachings of Becker, et al.



The Becker, et al., Patent demonstrates in figure 3 (above), that it is conventional in the art to use ink as a marker (50) in the outer wall of a catheter. Accordingly, based on the teachings of the cited patents, it would have been obvious for a person of ordinary skill in the art to enhance or modify the structure Ishida et al., with the use of ink as a marker in the outer surface of any portion of the catheter including the inflatable balloon.

Response to Arguments

Applicant's arguments filed November 14, 2005 have been fully considered but they are not persuasive. Applicant's remarks acknowledged that Ishida et al. teaches that the balloon can be mixed with X-ray opaque substance to turn the balloon into a

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marker. Therefore, for a person of ordinary skill in the art, any part of the balloon, expandable or not expandable, could be converted into a marker.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

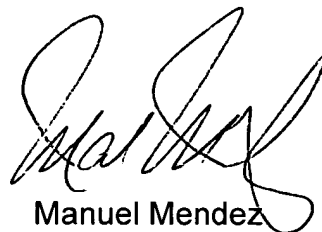
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully submitted,



Manuel Mendez
Primary Examiner
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